UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,069	12/12/2003	Matthias Frericks	920-9US (P10202US)	1279

570 7590 11/01/2005

AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,069	FRERICKS ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-29* is/are pending in the application.

4a) Of the above claim(s) *16-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 3–29 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

2. Additionally, Examiner notes an error correction in the Office Action mailed on 23 May 2005. Under the 35 USC § 102 rejection in paragraph number 12, the rejection regarding claim 5 should have referenced Bussard rather than Jenkins.

Election/Restrictions

3. Claims 16–27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 August 2005.

Specification

4. The disclosure correction is accepted.

Claim Objections

5. The claim corrections are accepted.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3–4, 14–15, and 28–29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skalsky et al. U.S. Patent 4,784,161, and in view of Munshi et al., U.S. Patent 5,683,443 and Gibbs et al., *A capacitance enhancement resulting form the interaction of platinum with alkali halides.*

Regarding Claim 1, Skalsky discloses an electrically conducting electrode base member formed of at least one metal selected from a group consisting of gold, carbon, platinum, iridium, platinum-iridium alloys (Figs. 14–19; column 9, lines 32–34) and stainless steel, wherein an electrode base member is partially covered with an electrically insulating ceramic layer, wherein a ceramic layer is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of titanium, niobium, tantalum, zirconium, aluminum (Figs. 2–5; column 5, lines 49–50; column 9, lines 41–43), and silicon, wherein an electrode base member is further at least partially coated with an electrically conducting layer comprising at least one material selected from a group consisting of titanium nitride, niobium nitride, tantalum nitride, zirconium nitride, aluminum nitride, silicon nitride, vanadium nitride, iridium oxide and an alloy of platinum and iridium (column 6, lines 20–22).

Skalsky does not disclose an iridium portion of the alloy is $\geq$ 21 wt. %. However, Munshi discloses an iridium portion of an alloy is $\geq$ 21 wt. % (column 24, lines 42–45) to

significantly reduce the polarization losses and improve the efficiency of the energy transfer through the tissue (column 8, lines, 61–63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Skalsky to include an iridium portion of an alloy is ≥ 21 wt. %, as taught by Munshi to significantly reduce the polarization losses and improve the efficiency of the energy transfer through the tissue (column 8, lines, 61–63).

Skalsky does not disclose a platinum portion of an alloy is ≥ about 100 ppm. However, Gibbs discloses a platinum portion of an alloy is ≥ about 100 ppm (page 1393, lines 17–20) to enhance capacitance and reduce conductance (page 1392, Abstract line 3 and page 1396, lines 9–10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Skalsky to include a platinum portion of an alloy is ≥ about 100 ppm, as taught by Gibbs to enhance capacitance and reduce conductance (page 1392, Abstract line 3 and page 1396, lines 9–10).

Regarding Claim 3, Skalsky discloses a ceramic layer is arranged on an electrically conducting layer (Fig. 2).

Regarding Claim 4, Skalsky discloses a ceramic layer is arranged adjacent an electrically conducting layer on an electrode base member (Fig. 2).

Regarding Claim 14, Skalsky discloses a ceramic layer has a surface closed in itself (Figs. 1–2).

Regarding Claim 15, Skalsky discloses a ceramic layer has plurality of independent surfaces (Fig. 5).

Regarding Claims 28–29, Skalsky discloses an electrode is implantable in a human and implanted as a cardiac pacemaker electrode or a neuro-stimulation electrode (column 2, lines 54–61).

9. Claims 5–7, 10, 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skalsky, Munshi, and Gibbs, as applied to claim 1 above, and further in view of Gelb et al., U.S. Patent 6,799,076.

Regarding Claims 5, 6, and 12, neither Skalsky, Munshi nor Gibbs discloses an electrically conducting layer is formed of titanium nitride nor an electrically conducting layer of titanium nitride is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member nor an oxidation protection layer has a thickness in a range of about 500nm to about 5 μm. However, Gelb discloses an electrically conducting layer is formed of titanium nitride (column 1, lines 65–66; column 2, lines 1–2; column 3, lines 41–45) and an electrically conducting layer of titanium nitride is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member (column 2, lines 6–8) and an oxidation protection layer has a thickness in a range of about 500nm to about 5 μm (column 3, lines 15–16) to achieve low polarization (column 3, lines 46–47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Skalsky, Munshi, and Gibbs to include an electrically conducting layer is formed of titanium nitride and an electrically conducting layer of titanium nitride is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member and an oxidation protection layer has a thickness in

a range of about 500nm to about 5 μm, as taught by Gelb to achieve low polarization (column 3, lines 46–47).

Regarding Claim 7, Skalsky discloses a ceramic layer is arranged on at least one oxidation protection layer (Fig. 2).

Regarding Claim 10, Skalsky discloses an oxidation protection layer is formed of at least one element selected from the group consisting of platinum, iridium, and gold (column 6, lines 19–21).

10. Claims 8 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skalsky, Munshi, Gibbs, and Gelb, as applied to claim 7 above, and further in view of Bussard et al., U.S. Patent 4,440,178.

Neither Skalsky, Munshi, Gibbs, nor Gelb discloses a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member or a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride. However, Bussard discloses a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member (column 2, lines 16–18 and 20; column 4, lines 5–6, 12–13, and 19–20) and a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride (column 2, line 20; column 4, lines 5–6, 12–13, and 19–20) to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly (column 1, lines 43–46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Skalsky, Munshi, Gibbs, and Gelb to include a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member and a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride, as taught by Bussard to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly (column 1, lines 43–46).

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skalsky, Munshi, Gibbs, and Gelb, as applied to claim 7 above, and in view of Bolz, U.S. Patent 5,609,611.

Neither Skalsky, Munshi, Gibbs, nor Gelb, discloses an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member. However, Bolz discloses an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member (Fig. 6) for picking up heart signals for which the low-frequency range is

particularly important, especially in the region where the signals are weak (column 8, lines 44–47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Skalsky, Munshi, Gibbs, and Gelb to disclose an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member, as taught by Bolz for picking up heart signals for which the low-frequency range is particularly important, especially in the region where the signals are weak (column 8, lines 44–47).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skalsky, Munshi, and Gibbs as applied to claim 1 above, and further in view of Schulman, U.S. Patent 6,844,023.

Neither Skalsky, Munshi, nor Gibbs discloses a ceramic layer has a thickness in a range of about 1 nm to about 20 μm. However, Schulman discloses a ceramic layer has a thickness in a range of about 1 nm to about 20 μm (column 2, lines 44–46) to protect microminiature components and devices intended to be implanted in living tissue (column 1, lines 16–18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Skalsky, Munshi, and Gibbs to include a ceramic layer has a thickness in a range of about 1 nm to about 20 μm, as taught by Schulman to

protect microminiature components and devices intended to be implanted in living tissue (column 1, lines 16–18).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
October 28, 2005
28 October 2005

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
10/28/05